



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,755	10/30/2001	Toshihiro Shimizu	2522 US2P	1478

23115 7590 03/03/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,755

Applicant(s)

SHIMIZU ET AL.

Examiner

Susan Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/03/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,11-19,21-33,36,38-44 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,11-19,21-33,36,38-44 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5 and 9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Terminal Disclaimer filed 11/25/02, Supplemental Information Disclosure Statement and Amendment filed 12/03/02.

Terminal Disclaimer

The terminal disclaimer filed on 11/25/02 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of USPN 6,328,994 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

The references A4-a10 listed on the information disclosure statement (IDS) submitted on 10/30/01 was filed after the mailing date of the Office Action on 09/04/02. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-7, 9, 11-19, 21, 22, 24, 31-33, 36, 38-44, and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimizu et al. (339).

Shimizu teaches effervescent composition comprising a core-shell powder surrounding a fine granular core spray-coated with water-soluble polymer, physiologically active substance, and enteric coating layer (see abstract and column 3). The fine granular core having average diameter of about 250 μm , includes crystalline cellulose and 50-70% lactose beads (columns 4-5). The composition further comprises additives, such as, crystalline cellulose, mannitol, lactose, magnesium or calcium carbonate, and mixture thereof (column 6, lines 36-51). The physiologically active substance layer further comprising 0.1 to about 50% low-substituted hydroxypropylcellulose (I-HPC), (see columns 6-7). The amount of active substance is disclosed throughout the examples.

The examiner notes that Shimizu is silent as to the teaching of the tablet hardness. However, it is the position of the examiner that the particular tablet hardness is inherent since Shimizu is using the same ingredients to obtain the same result desired by the applicant, *i.e.*, tablet dosage form of effervescent fine granules containing acid-labile drug.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33, 36, 38-44, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. (339), in view of Kamada EP 0 452 862 A2.

Shimizu is relied upon for the reasons stated above. Applicant alleges that Shimizu does not teach a sustained release agent, nor does it identify additives which could be equated to the sustained-release agent of the present invention.

Kamada teaches spherical core being coated with powder layer comprising active ingredients and having an out layer of coating (see abstract). The coating agents can be used alone or in a combination thereof, which includes acrylic polymers, cellulosic polymer, shellac, or the like (page 5, lines 1-14). Thus, it would have been obvious for one of ordinary skill in this art to modify Shimizu's coating agents using the mixture of coating in view of the teaching of Kamada to obtain the claimed invention because the references teach the advantageous results in the use of similar coating agents for acid-labile active drug. The expected result would be effervescent tablet dosage form of fine granules containing acid-labile drug, which will provide accurate controlled release rate.

Art Unit: 1615

Claims 1-7, 9, and 11-19, and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. (339) and Kamada, in view of Shimizu et al. US 6,299,904 (904). The examiner relies on the date of the foreign application of Shimizu (904), which is 05/27/97. The translation copy will be provided in the next office action communication.

Shimizu (339) and Kamada are relied upon for the reasons stated above. The references are silent as to the teaching of tablet hardness.

Shimizu (904) teaches quick disintegrable solid pharmaceutical composition comprising 0.01 to 70% acid-labile active ingredient; 5 to 97% of one or more water-soluble sugar alcohols, e.g., erythritol, maltitol, or sorbitol; and low-substituted HPC having hydroxypropoxyl group contents of 7.0 to 9.9% (abstract, and columns 2-5). The composition further comprises about 3 to 50% of crystalline cellulose (columns 5-6). The solid dosage form is disintegrated within 50 seconds and having hardness of about 2 to about 20 kg (columns 7-8). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify Shimizu (339), using the sugar alcohol in view of the teaching of Shimizu (904), because the references teach the advantageous results in the use of sugar alcohol to obtain a disintegrable oral dosage form. The expected result would be a disintegrable tablet having quick dissolution rate and appropriate hardness strength.

Response to Arguments

Art Unit: 1615

Applicant's arguments filed 12/03/02 have been fully considered but they are not persuasive.

Applicant argues that Shimizu does not teach a sustained release agent, nor does it identify additives which could be equated to the sustained-release agent of the present invention. Contrary to the applicant's argument, Shimizu teaches coating agent can be HPMC, cellulosic polymer, Tween 80, Pluronic, castor oil, *acrylic copolymers* (*Eudragit*®), shellac, was^X_X talc, titanium dioxide, *and* red iron oxide (column 7, lines 7-21, and column 9, lines 50-67). Accordingly, such language does suggest a sustained release agent, or additives which could be equated to the sustained-release agent.

Applicant argues that Shimizu '904 does not cure the deficiencies of Shimizu '339. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant further alleges that the '904 reference is not properly cited art due to applicant's earlier priority dated 05/18/1998. The examiner relies on the foreign priority date of the '904 reference, which is 05/27/97. The examiner apologizes for the delay of a translation copy of the JP 9-136724, it will be provided in the next office action communication.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/03/03 prompted the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached from Monday through Thursday from 6:00 am to 4:30 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 4:30 pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615